

Application No. 09/815,573  
Response Dated December 2, 2005  
Reply to Office Action of September 2, 2005

**REMARKS**

In the Office Action dated September 2, 2005, claims 8-14 were examined with the result that all claims were rejected. The Examiner made the rejection final. In response, Applicant has filed a Request for Continuing Examination (RCE) and submits the following comments. In view of these comments, reconsideration of claims 8-14 is herein requested.

In the Office Action, claims 8-14 were rejected under 35 USC §103(a) as being unpatentable over DeLuca et al WO 96/24258. The Examiner states that the '258 reference describes a method of improving utilization of phytate phosphorus so as to reduce or minimize or perhaps eliminate dietary requirements of phosphorus in animals, including dairy cows. In view of this teaching, the Examiner believes that it would be obvious to one of ordinary skill in the art to replace all inorganic phosphorus in a diet for a lactating dairy cow with an effective amount of a 1 $\alpha$ -hydroxylated vitamin D compound, as claimed by Applicant. Applicant, however, respectfully disagrees for the following reasons.

It is recognized by all those skilled in the art of animal husbandry that lactating dairy cows require sufficient phosphorus (P) in their diets in order to maintain milk yields as well as good health. Typically, a normal diet for dairy cows contains about 0.9% phosphorus, and one skilled in the art knows that dairy cows must have sufficient phosphorus in order for the dairy cow to maintain adequate milk yields. See for example, the enclosed article entitled "Tables of Nutrient Requirements" found in Chapter 9 of Nutrient Requirements of Beef Cattle, 7th Revised Edition, Update 2000, pages 102-112. A phosphorus deficiency, especially in dairy cows, also may have serious health consequences. See for example, the enclosed article entitled "Nutrient Requirements of Dairy Cattle" 7th Revised Edition, Update 2001, pages 114-117, especially pages 115-116. Thus, one skilled in the art would not have fed a low phosphorus diet to a dairy cow because it is readily recognized that a feed supplement without any inorganic phosphorus in the cow's diet would not meet the

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minimum P requirements for the animal, and would result in various toxic situations. Thus, it is important for the Examiner to understand that calling for the replacement of all inorganic phosphorus in a diet for a dairy cow with a vitamin D compound is clearly in contrast to conventional thinking, and one skilled in the art would not readily accept that all inorganic phosphorus supplements could be eliminated while still maintaining high milk yields in dairy cows. One of the important points to keep in mind is the requirement that the dairy cow maintain high milk yields. While it may be possible to replace supplemental inorganic P in other animals, dairy cows are especially sensitive to changes in diet, and any reduction and/or elimination of inorganic P cannot be made at the expense of milk yields. Thus, any diet which eliminates inorganic P supplements must ensure that milk yields do not decline. The idea that one can eliminate inorganic P supplements while maintaining milk yields is a concept that is simply contrary to what would be accepted by one skilled in the art.

The Examiner states that it would be obvious to eliminate or replace all inorganic phosphorus in a diet for a dairy cow because the DeLuca et al '258 reference refers to the possibility of minimizing, or "perhaps" eliminating, the need for supplemental quantities of P in an animal diet by incorporating  $1\alpha$ -hydroxylated vitamin D compounds in the animal's diet. The Examiner latches on to the word "perhaps" found in the Abstract of the '258 reference and states that this provides the motivation for one skilled in the art to eliminate or replace all inorganic phosphorus in the diet of a dairy cow. Although the '258 reference never mentions dairy cows, the Examiner refers to page 10, line 10 of the '258 reference for its reference to "cattle" and then states that dairy cows are "cattle" and thus the description in the '258 reference suggests the elimination of all inorganic phosphorus in dairy cows. However, the word "perhaps" is defined as "a possibility but not a certainty." Such definition is clearly not an affirmative teaching, much less a suggestion, to one skilled in the art that one can eliminate all P in a dairy cow's diet and maintain milk production in the dairy cow. The word "perhaps" implies that further work

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needs to be performed in order to determine whether something is a certainty. This falls far short of suggesting to one skilled in the art that all supplemental inorganic P can be replaced in a dairy cow's diet and still maintain adequate milk yield.

In the Office Action, the Examiner also stated that the test results set forth in Applicant's specification do not support Applicant's claim because none of the tests shown in Tables 2-4 are directed toward 0% phosphorus in the diet. The Examiner, however, has misinterpreted the data. Turning to Table 1, the Examiner will note that the high P diet contains 0.4% sodium monophosphate. However, the low P diet contains 0% sodium monophosphate. Thus, the low P diet contains no inorganic P. The Examiner correctly notes that the high P diet contains 0.47% P and the low P diet contains 0.35% P. In the high P diet there is both phytate bound phosphorus and the inorganic phosphorus found in sodium monophosphate. In contrast, in the low P diet, there is only phytate phosphorus. This accounts for the difference between 0.47% P in the high P diet and 0.35% P diet in the low P diet. Reference is further made to page 11, lines 15-18 wherein the four treatments are defined with treatment 2 being the high P diet plus the vitamin D compound and treatment 4 being the low P diet plus the vitamin D compound. Turning to the results illustrated in Table 2 at the top of page 16, one can see that the treatments 2 and 4 both maintained adequate milk yields of 36.9 kilograms per day and 37.6 kilograms per day respectively. This is further referred to in the description at page 14, lines 1-5. Thus, contrary to the Examiner's statement that the data does not support Applicant's claim 1, the data clearly do support Applicant's claim 1 by evidencing the fact that a diet without any inorganic P plus the vitamin D compound results in the maintenance of milk production in a dairy cow fed a low phosphorus diet, i.e. one without any inorganic phosphorus supplementation.

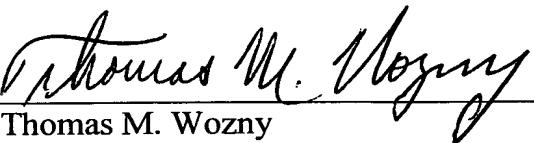
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An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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